

K962445

JUL 30 1996

ArthroCare Corporation
Sunnyvale, California
Premarket Notification
June 21, 1996

X. 510(k) Summary

A. *Name of Device*

Trade name: ArthroCare Dental Electrosurgery System
Common name: Dental Electrosurgical Unit
Classification name: Dental Electrosurgical Unit and Accessories
(21 CFR 872.4920)

B. *Predicate devices*

<u>Device</u>	<u>Premarket Notification</u>
ArthroCare Arthroscopic Electrosurgery System	K943450
ArthroCare Bipolar Loop Electrosurgery System	K955531
ArthroCare Urologic Multi-electrode Electrosurgery System	K961069
Parkell 500SE Sensimatic Electrosurge	K952039

C. *Device description*

The ArthroCare Dental Electrosurgery System is comprised of three components: the Dental Probe, the Probe Cable, and an electrosurgical generator called the Controller. The Probe Cable connects the Controller to the Probe. The Probe is provided in a variety of models, ranging in diameters from 0.5 mm to 2.5 mm with the distal tip of the probe as straight or bent at angles up to 90 degrees. The distal tip may be configured with multi-electrodes or as a loop electrode. The Probe is supplied sterile and intended for single patient use. The Probe Cable is designed for repeat sterilization by either ethylene oxide gas or steam autoclaving methods, as selected by the user. The Controller is a high frequency electronic instrument. There is no software utilized in the operation of the Controller.

The ArthroCare Dental Electrosurgery System is bipolar, incorporating a return electrode on the shaft of the device. This means that a return pad is not required for operation. The return energy in a bipolar device with an integral return electrode does not penetrate the tissue as in a monopolar device. In a monopolar device, the energy passes through the patient's body to reach the return pad.

D. Intended use

The ArthroCare Dental Electrosurgery System is intended for use in dental and periodontal surgical procedures to remove soft tissue and to control bleeding in the oral cavity.

E. Technological characteristics

The technological characteristics of the ArthroCare Dental Electrosurgery System are the same as those of the ArthroCare Arthroscopic, Bipolar Loop and Urologic Multi-electrode Systems. These devices are equivalent in terms of design, materials, principle of operation, product specifications and sterilization.

F. Summary

By virtue of design, materials, function and intended use, the ArthroCare Dental Electrosurgery System is substantially equivalent to devices currently marketed in the United States.